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MATCH: A multidisciplinary approach to the advancement of Health Technology Assessment

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Background and purpose

The importance of health technology as an expanding market for the UK economy is becoming widely recognised. Consequently, progress needs to be made to help stimulate its growth [1] whilst simultaneously ensuring that the products offered will truly benefit the consumers. To this end the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH) [2] initiative has been created via EPSRC funding for an initial period of five years. This is a 'virtual centre' across five UK universities (Birmingham, Brunel, Kings College London, Nottingham and Ulster) involving a research programme that aims to improve the methods used to produce and assess value of all manner of medical devices from concept through to mature product.

In addition to the academic involvement, MATCH includes the active participation of a cohort of subscribing industrial partners, the Department of Trade and Industry (who are providing subsidies for SMEs), Invest Northern Ireland and the National Patient Safety Agency.

Multiple perspectives of value assessment

The complexity of medical device assessment lies in its multiple perspectives and developing products or investing in the sector can be a daunting process. 'Picking a winner' has to be measured in terms of the time and funds required to traverse the complex route from concept to mature product including navigation of the regulatory pathways, versus a return that may be difficult to predict compared, for example, to pharmaceutical products. All medical devices must obviously function reliably and safely whilst being suitable for volume manufacture at the appropriate scale and conforming to a variety of standards in design, production and quality management [3].

Concerning production processes, the world is moving from more general ISO9000 standards to those specific to medical devices such as ISO13485, putting them in line with EU Medical Device directives and FDA approval processes in the USA. Costs to meet regulatory requirements must be borne early on in the product lifecycle. Obtaining wider approval (e.g. outside Europe) may benefit from prior CE-Marking.

For the user (patient or clinician depending upon the device type) the product must be ergonomically and

socially acceptable whilst performing its intended medical function. Furthermore, there is a trend towards encouraging increased patient participation in their own healthcare, via such agencies as the Expert Patient self-management programme in the NHS [4].

For reimbursement agencies, whether publicly or privately managed, the product must be cost effective as well as having a proven clinical effectiveness and appropriate safety record. Within the NHS this requirement is typified by the National Institute of Clinical Excellence (NICE) interaction with the Health Technology Assessment (HTA) programme [5]. Forces may also act in areas such as the ethics of, and equity of access to, healthcare delivery.

The MATCH approach

In order to address these issues in a holistic manner, MATCH has assembled a multidisciplinary team comprising biomedical engineers, clinicians, health economists, social scientists and ergonomists.

The main research themes within MATCH concern the 3 areas of: the design and use of appropriate decision-making processes; manufacturing processes and regulatory procedures for healthcare devices; and methodologies for addressing user needs. The relevance of this research to the healthcare industry will be ensured via close liaison with industrial partners with whom we will work on the development of exemplar products. In addition to the usual means of dissemination the programme will be producing best practice guides.

Initial results and conclusions

MATCH has set up a tiered approach to involving industry partners, who are able to join under differing schemes appropriate to their required level of involvement and needs, numbering around 30 medical device manufacturers and related suppliers to date. We have been conducting interviews to gauge similarities and differences in the problems they face, and will present our initial findings.

References

- [1] Department of Health: Health Industries Task Force, <http://www.advisorybodies.doh.gov.uk/hitf>
- [2] Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH), <http://www.match.ac.uk>
- [3] EUROPA EC Enterprise: Medical Devices, http://europa.eu.int/comm/enterprise/medical_devices
- [4] NHS: Expert Patients Programme (EPP), <http://www.expertpatients.nhs.uk>
- [5] Health Technology Assessment programme, <http://www.hta.nhsweb.nhs.uk>